



General Assembly

January Session, 2005

Raised Bill No. 1286

LCO No. 4257

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Referred to Committee on Public Health

Introduced by:
(PH)

***AN ACT REQUIRING DISCLOSURE OF INFORMATION FROM
CLINICAL TRIALS.***

Be it enacted by the Senate and House of Representatives in General Assembly convened:

1 Section 1. (NEW) (*Effective from passage*) (a) On and after the effective
2 date of this section, no health care provider or institution and no public
3 or private institution of higher education located in this state shall
4 participate in a clinical trial involving (1) the safety or effectiveness of a
5 new drug or device, or (2) the safety or effectiveness of an existing
6 drug or device for an additional indication, unless the drug
7 manufacturer and the person responsible for the clinical trial agree to
8 (A) register the clinical trial in advance with the National Institutes of
9 Health for inclusion in the institute's on-line clinical trial database, and
10 (B) fully and publicly disclose the results of the clinical trial through
11 either publication or an electronic repository.

12 (b) Nothing in this section shall be construed to require the
13 disclosure of information concerning a method or process that is a
14 trade secret entitled to protection within the meaning of Section 301(j)
15 of the federal Food, Drug and Cosmetic Act.

16 (c) The Commissioner of Public Health shall adopt regulations, in
17 accordance with the provisions of chapter 54 of the general statutes, to
18 carry out this section.

19 (d) For purposes of this section, "health care provider" means any
20 person, corporation, limited liability company, facility or institution
21 operated, owned or licensed by this state to provide health care or
22 professional services, or an officer, employee or agent thereof acting in
23 the course and scope of such person's employment; and "institution"
24 has the same meaning as provided in section 19a-490 of the general
25 statutes.

This act shall take effect as follows and shall amend the following sections:		
Section 1	<i>from passage</i>	New section

Statement of Purpose:

To make clinical drug trial results available to physicians and consumers.

[Proposed deletions are enclosed in brackets. Proposed additions are indicated by underline, except that when the entire text of a bill or resolution or a section of a bill or resolution is new, it is not underlined.]